

## **NOTICE OF PROPOSED RULEMAKING**

### **California Coronary Artery Bypass Graft Outcomes Reporting Program**

NOTICE IS HEREBY GIVEN that the Office of Statewide Health Planning and Development (OSHPD) proposes to amend Sections 97170, 97172, 97174, 97178, 97180, 97184, 97188, 97190, and 97198 of Title 22 of the California Code of Regulations (CCR). This amendment will add, change, and delete certain reporting data elements in the California Coronary Artery Bypass Graft Outcomes Reporting Program (CCORP) and make minor program changes.

### **PUBLIC HEARING**

A public hearing has been scheduled on September 6, 2005 starting at 10:00 a.m. at the Bateson Building located at 1600 9<sup>th</sup> Street, Room 441, Sacramento, California 95814. The Bateson Building is wheelchair accessible. At the hearing, any person may present statements or arguments orally or in writing relevant to the proposed action. OSHPD requests but does not require that persons who make oral comments at the hearing also submit a written copy of their testimony at the hearing.

### **WRITTEN COMMENT PERIOD/CONTACT PERSON**

Any interested person may submit written comments relevant to the proposed regulatory action. All such comments must be received by OSHPD 5:00 p.m. on September 6, 2005.

All inquiries and comments concerning the proposed regulations should be addressed to the primary contact person named below. Comments may be delivered by fax, e-mail, hand delivery, or mail to:

Hilva Chan, Manager  
Clinical Data Programs  
Healthcare Outcomes Center  
Office of Statewide Health Planning and Development  
818 K Street, Suite 200  
Sacramento, CA 95814  
Tel: (916) 322-9137  
Fax: (916) 322-9718  
E-mail: [hchan@oshpd.state.ca.us](mailto:hchan@oshpd.state.ca.us)

Inquiries and comments may also be addressed to backup contact person Joseph Parker, Ph.D., Director, Healthcare Outcomes Center, Office of Statewide Health Planning and Development, 818 K Street, Suite 200, Sacramento, CA 95814, Tel: (916) 322-9298, Fax: (916) 322-9718, E-mail: [jparker@oshpd.state.ca.us](mailto:jparker@oshpd.state.ca.us).

All comments should include the author's name and U.S. Postal Service mailing or e-mail address in order for OSHPD to provide copies of any notices for proposed changes in the regulation text on which additional comments may be solicited.

## AUTHORITY AND REFERENCE

Pursuant to the authority vested by Section 128810 of the California Health and Safety Code, OSHPD proposes to amend Sections 97170, 97172, 97174, 97178, 97180, 97184, 97188, 97190, and 97198 of Chapter 10 of Division 7 of the California Code of Regulations, which would implement, interpret, or make specific Sections 128745 and 128748 of the Health and Safety Code.

## INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Existing law established CCORP under Health and Safety Code Sections 128745 and 12748. It requires OSHPD to publicly report risk-adjusted CABG outcomes for all hospitals and surgeons. It also requires OSHPD to appoint a nine-member Clinical Advisory Panel (CAP) to review and approve the development of the risk adjustment model used for CABG surgery, and make recommendations on the addition, revision and deletion of clinical data elements collected for the CABG surgery outcome reports.

The proposed amendments below were recommended by the CAP on its July 26, 2004 and April 27, 2005 meetings. These proposed actions will add, delete, and change certain required data elements and make minor program changes to CCORP. The purpose of the proposed regulation action is three-fold:

- a. To maintain data consistency among reporting hospitals by revising CCORP data elements to reflect the changes in the Society of Thoracic Surgeons (STS) Adult Cardiac Surgery Database
- b. To improve the CCORP risk model by adding, changing and deleting the CCORP data elements based upon recommendations by the CAP. All the newly added data elements are STS data elements.
- c. To improve the CCORP hospital data reporting process by making minor program changes

By doing so, the proposed amendments would improve the public reporting of CABG surgery outcomes in California. CCORP reports would better reflect the quality of care provided by California hospitals on CABG surgery.

OSHPD has considered the following two factors before adding data elements from the STS data base:

1. We found it not feasible to utilize sampling because we cannot use data collected from a sample of hospitals to determine outcomes for all hospitals in our public reports.

2. To the extent possible, we exchanged data with STS. Of the four deleted CCORP data elements, two were replaced by new STS data elements in version 2.52.

OSHPD has determined that there are no comparable federal regulations, and the proposed changes are not mandated by federal law or regulations.

OSHPD has determined that the regulations have been drafted in plain English.

The proposed change to CCR Section 97170 clarifies the term 'discharge' as used in the CCORP regulations.

The proposed change to CCR Section 97172 provides a technical correction to the regulations.

The proposed changes to CCR Section 97174 improve CCORP data quality by ensuring that all hospitals report the same data elements to CCORP. The proposed revisions should also improve the CCORP risk model performance.

The proposed change to CCR Section 97178 provides more flexibility for hospitals to file an extension.

The proposed change to CCR Section 97180 improves data quality by requiring hospitals that do not use the CCORP data collection tool to file a test file, if certain conditions are met.

The proposed change to CCR Section 97184 clarifies the paperwork requirements for submitting CCORP data. This should help prevent unnecessary data rejection due solely to paperwork problem.

The proposed change to CCR Section 97188 clarifies the paperwork requirements for submitting CCORP data. This should help prevent unnecessary data rejection due solely to paperwork problem.

The proposed CCR Section 97190 provides minor revisions to the CCORP Hospital Certification Form.

The proposed change to CCR Section 97198 clarifies that a hospital is not considered delinquent if an extension request was granted by the Office.

## DISCLOSURES REGARDING THE PROPOSED ACTION

OSHPD has made the following initial determinations:

1. Local mandate: None.

2. Estimated cost or savings to any state agency: An estimated cost of \$25,000 for revising the existing CCORP data collection tool.
3. Cost to any local agency or school district that is required to be reimbursed by the state in accordance with Government Code Sections 17500 through 17630: None.
4. Non-discretionary cost or savings imposed on local agencies: None.
5. Cost or savings in federal funding to the state: None.
6. Significant impact on housing costs: None.
7. Potential cost impact on private persons or affected businesses: The estimated annual cost to comply with the proposed regulatory action for a non-STS hospital is \$1,151. There is no cost for a STS hospital.
8. Potential adverse economic impact on business: OSHPD has determined that the regulations would not have a significant, statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.
9. OSHPD has determined that the regulations would not significantly affect the following:
  - 1) The creation or elimination of jobs within the State of California.
  - 2) The creation of new businesses or elimination of existing businesses within the State of California.
  - 3) The expansion of businesses currently doing business within the State of California.
10. Business reporting requirement: OSHPD finds that it is necessary for the health, safety, or welfare of the people of this state that proposed sections 97170 through 97198, which require reporting, apply to businesses.
11. Small business determination: The proposed regulatory action does not affect small business. The health care facilities affected by the action either have more than 150 beds or more than \$1,500,000 in annual gross receipts. In accordance with Government Code Section 11342.610, these health care facilities are not defined as small businesses.

### ALTERNATIVES CONSIDERED

OSHPD has determined in accordance with Government Code Section 11346.5(a)(13) that no reasonable alternative considered by OSHPD or that has otherwise been

identified and brought to the attention of OSHPD would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed action.

#### AVAILABILITY OF STATEMENT OF REASONS, TEXT OF PROPOSED REGULATIONS AND RULEMAKING FILE

OSHPD has prepared an initial Statement of Reasons for the proposed regulations. This statement, the express terms of the proposed regulations, and the information upon which the proposal is based, are available by contacting the contact person above. In addition, the Initial Statement of Reasons and the proposed text amendments can be accessed through OSHPD's web site at <http://www.oshpd.ca.gov/HQAD/About/laws.htm#CCORP>

#### AVAILABILITY OF CHANGED OR MODIFIED TEXT

After holding the hearing and considering all timely and relevant comments received, the Office may adopt the proposed regulations substantially as described in this Notice. If the Office makes modifications that are sufficiently related to the originally proposed text, it will make the modified text (with the changes clearly indicated) available to the public for at least 15 days before the Office adopts the regulations as revised. Please send requests for copies of any modified regulations to the contact person as listed in this Notice. The Office will accept written comments on the modified regulations for 15 days after the date on which they are made available.

#### AVAILABILITY OF FINAL STATEMENT OF REASONS

Upon its completion, copies of the Final Statement of Reasons may be obtained by contacting the contact person as listed in the Notice.